BENEFITS AND PUBLIC INTEREST FINDINGS FOR REGISTRATION OF DICAMBA FORMULATIONS FOR USE ON DICAMBA AND GLYPHOSATE TOLERANT CROPS

TEST GUIDELINE

Not Applicable

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Benefits and Public Interest Findings for Registration of Dicamba Formulations for Use on Dicamba and Glyphosate Tolerant Crops

1. Introduction

Effective and efficient weed control is essential for agricultural productivity. Crops genetically engineered to tolerate broad spectrum herbicides revolutionized agricultural weed management but herbicide resistance has increased, threatening the efficacy and efficiency of current models. The introduction of crops engineered to tolerate two or more herbicides provides an additional technology to address this challenge and control herbicide resistant weeds.

Monsanto Company has introduced a formulation of the herbicide, dicamba, that can be applied over the top (OTT) of soybean and cotton to control glyphosate resistant weeds. This document reviews the benefits of registering dicamba for OTT uses in soybean and cotton to demonstrate that such registrations are in the public interest.

Amending the expiration date to enable continued OTT applications of dicamba for soybean and cotton will continue to promote diversified weed management to control the risk of additional herbicide resistance. It will also allow the current benefits of herbicide tolerant cropping systems to continue, notably reduced tillage. Finally, OTT dicamba, as part of diversified weed management systems produces positive economic returns for growers such that they are encouraged to use this technology while employing weed management tactics that promote sustainability and maintain the leading U.S. position on key crop production and export.

2. Background

Soybeans and cotton are extremely important agricultural commodities in the United States and the world. According to the USDA's Economic Research Service (USDA-ERS), soybeans are grown on approximately 89 million acres and cotton is grown on approximately 11 million acres in 2018 (USDA-ERS, 2018). USDA-ERS describes soybeans as the world's largest source of animal protein feed and the second largest source of vegetable oil, and describes cotton as one of the most important textile fibers in the world, accounting for around 35 percent of total world fiber use (U.S. EPA, 2016). The U.S. is the world's leading soybean producer and exporter. USDA estimates 2018/2019 gross value of soybean production in the U.S. at approximately $40.3 billion. USDA estimates 2018/2019 gross value of cotton production in the U.S. at over $7.1 billion (USDA-ERS, 2018).

Effective and cost-efficient weed control is essential for agricultural productivity. Experts identify weeds as the primary threat to crop production. On an annual basis, potential loss in value for soybean is $16 billion based on data from 2007 to 2013 (Dille et al., 2016). Overall, average percent yield loss with no weed control in soybean is 49.5%. Prior to the widespread adoption of herbicides in the mid twentieth century, farmers relied on mechanical controls such as tillage and hand weeding. Herbicide adoption reduced the need for hand weeding (Gianessi and Reigner 2006) and the introduction of crops genetically engineered to tolerate broad spectrum herbicides further simplified weed control (Fernandez-Cornejo et al., 2007).

Gardner et al. (2009) investigated the role of herbicide tolerant crops in reducing farm labor requirements by examining USDA Agricultural Resource Management Survey data. They found that the average soybean farmer with 517 acres reduced labor requirements 14.5% by adopting herbicide tolerant soybeans. This reduction resulted in a total requirement of 94.5 hours of labor per growing season, allowing the extra time to be devoted elsewhere, including off-farm employment. Marra and Piggott (2006) documented that farmers who grow herbicide tolerant crops place a monetary value on the labor savings they experience.

The first generation of genetically engineered herbicide tolerant crops were resistant to a single herbicide, typically glyphosate. Reliance on a single herbicidal mechanism of action to control weeds can lead to resistant weed biotypes. As has been the case in the past, natural selection of tolerant weeds has meant that growers have needed to continue to adapt and implement evolving weed management strategies. These types of adaptations in resistance management strategies are not new as weed resistance has occurred for decades, well before the introduction of herbicide-tolerant crops.

As of October 2018, 495 herbicide-resistant weed biotypes have been reported to be resistant to 21 different herbicide mechanisms-of-action worldwide (Heap, 2018). Dicamba-resistant weeds account for 1% of resistant biotypes respectively (Heap, 2018). Again, resistance occurs naturally in weed populations, and the use of herbicides selects for the resistant plants within a population. As discussed further below, Monsanto continues to rely upon the consensus recommendations of leading academic weed scientists who, for several years, have recommended multiple mechanisms of action.

Where necessary to manage herbicide-resistant weeds in soybean and cotton production, growers in certain areas of the U.S. have increased herbicide application rates, increased the number of herbicides (number of mechanisms of action), and, in some cases, returned to more traditional tillage practices (Monsanto, 2013) and hand-weeding (Culpepper, et al. 2011; NRC 2010). In an effort to manage glyphosate-resistant Palmer amaranth, certain non-glyphosate herbicides have been reported as being used in conditions and practices that have the potential to result in increased selection of resistant biotypes to those herbicides, thereby putting certain agricultural herbicides in some major herbicide classes at risk (Nichols, et al. 2010; Prostko 2011). While a limited number of effective options for managing Palmer amaranth, waterhemp, and other key broadleaf weeds exist, weed scientists have concluded that there is a need for additional herbicidal sites of action to mitigate the potential for development of resistance to the key herbicides essential for weed management in soybean and cotton (Tranel, et al. 2010).

In addition, there has been an increase in the detection of weed populations with resistance to multiple herbicidal sites of action (multiple resistance) in certain weed species, for example, *Amaranthus* spp. (Tranel et al. 2010). The emergence of these resistant biotypes demonstrates the continued need to utilize diversified weed management practices, including the need for additional herbicidal sites of action that are effective in major crops. The Weed Science Society of America (WSSA) reports: "Weed scientists know that the best defense against weed resistance is to proactively use a combination of agronomic practices, including the judicious use of herbicides with alternative mechanisms of action either concurrently or sequentially" (WSSA, 2010).

Today in U.S. soybean and cotton growing areas the weed species of most concern are broadleaf species, specifically summer annual species such as Palmer amaranth and waterhemp. Dicamba is an effective herbicide on these and other targeted summer broadleaf species, is compatible and complementary to glyphosate and is an essential tool to assist growers to effectively manage weeds and weed resistance in general. Recently, a Missouri soybean grower and an academic weed scientist reported a variety of waterhemp (*Amaranthus sp.*) resistant to six herbicides, including 2,4-D (Begemann, 2018). Notably, dicamba was still an effective control. The ability to use dicamba in conjunction with dicamba tolerant crops offers growers an additional option to manage broadleaf weeds at a time when current herbicide options are becoming more limited as biotypes with resistance to multiple herbicide sites of action spread.

Figures 1 and 2 present overviews of herbicide resistant weeds in states where over the top (OTT) applications of dicamba are registered and case studies in three key states for soybean or cotton production. From the information in these figures, it is clear that limiting the herbicidal sites of action available to growers has the potential to prevent them from effectively controlling herbicide resistant weeds already present in their crops.

Dicamba tolerant weed management systems are used in combination with other herbicides including glyphosate, glufosinate and other soil residual and postemergence active herbicides currently labeled for use in either soybean or cotton. In soybean, there are three basic weed management systems today: a diversified system including multiple herbicides with different mechanisms of action, herbicides combined with non-herbicide management options, and, to a lesser degree, systems that still rely solely on glyphosate. In cotton, most farmers in the southeast, mid-south and Texas regions are using diversified weed management programs today, whereas cotton farmers in the western states are primarily relying only on glyphosate.

3. Public Interest Finding

EPA criteria for determining for assessing public interest are set forth in a Federal Register Notice dated March 5, 1986 (51 Federal Register (FR) 7628). There is a presumption that registration of a pesticide chemical is in the public interest if one of the following criteria is met: (1) the use is for a minor crop; (2) the use is a replacement for another pesticide that is of continuing concern to the Agency; (3) the use is one for which an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) has been granted (i.e., the basis for the exemption was lack of a registered alternative product); or (4) the use is against a pest of public health significance. Further, the Environmental Protection Agency (EPA) may determine that such a registration is in the public interest on the basis of the following criteria: (1) there is a need for the new chemical that is not being met by currently registered pesticides; (2) the new pesticide is comparatively less risky to health or the environment than currently registered pesticides; or (3) the benefits (including economic benefits) from the use of the new active ingredient exceed those of alternative registered pesticides and other available non-chemical techniques.

The registration of dicamba for use on glyphosate and dicamba tolerant crops is in the public interest given enhanced control of glyphosate resistant weeds by the addition of a second mechanism of action and because it will preserve the benefits (including economic benefits) of existing herbicides as indicated by the following factors:

i. Need for diversified weed management in corn, cotton and soybean production.

In-crop weed control is critically important for avoiding yield loss from late season weed flushes. However, post-emergent use of herbicides other than dicamba and glyphosate with Roundup Ready 2 Xtend Soybean, and dicamba, glyphosate and glufosinate with XtendFlex Cotton, is severely limited by: 1) the risk of crop damage from post-emergence application of herbicides the crop is not engineered to tolerate (Sarangi and Jhala, 2015); and 2) weed resistance that has rendered a growing number of post-emergent herbicides ineffective against key weed species in soybean and cotton cropping systems (Heap, 2018).

A prominent strategy to mitigate the evolution and development of herbicide-resistant weeds is to increase the diversity of weed management practices used in a particular cropping system. Diversified weed management practices use a combination of cultural (e.g., crop rotation), mechanical (e.g., cultivation), and herbicide control practices, including use of herbicides with different mechanisms of action (Duke and Powles 2009). Simultaneously using two herbicides with different mechanisms of action significantly reduces the probability of weeds developing resistance to either or both herbicides (Powles et al., 1996; Beckie and Reboud, 2009). Allowing flexibility in application timing by adding OTT uses will provide growers more opportunities to control weeds and prevent escapes.

Glyphosate has had few cases of weed resistance, particularly in comparison to other herbicides. In the U.S., while there have been thirteen confirmed glyphosate-resistant weeds (Heap, 2018), glyphosate still controls more than 160 weed species (Roundup WeatherMax herbicide label, EPA Reg. No.524-537) and remains an extremely valuable tool for U.S. crop production.

Dicamba is an excellent option to mitigate the potential for resistance to other herbicides because of its broad spectrum activity on broadleaf weeds and low level of weed resistance, specifically on the summer spectrum of weeds known to infest soybean and cotton acres. Dicamba is a synthetic auxin herbicide that kills plants by mimicking naturally-occurring plant growth hormones called auxins, thereby destroying tissue through uncontrolled cell division and growth (Ahrens, 1994). Dicamba's mechanism of action is different from glyphosate, and it provides efficacious control of broadleaf weeds and is complementary to glyphosate on hard to control weeds such as common lambsquarters, hemp sesbania, morning glory species, nightshade, Pennsylvania smartweed, prickly sida, velvetleaf, waterhemp, and wild buckwheat (Johnson et al., 2010). Additionally, dicamba provides effective control of herbicide-resistant broadleaf weeds, including glyphosate-resistant weeds such as marestail, common ragweed, giant ragweed, palmer pigweed, and waterhemp (Johnson et al., 2010). Hard-to-control weeds generally require a higher rate and/or application at a smaller growth stage in order to consistently achieve commercially acceptable control. Refer to the Roundup WeatherMax label (U.S. EPA Reg. No. 524-537) for a listing of these weeds. Herbicide resistant weeds are those listed on the International Survey of Resistant Weeds website (www.weedscience.org).

Dicamba is an effective broadleaf herbicide and using the potential dicamba and glyphosate herbicides at the same time in mixtures for weed control provides growers greater application flexibility prior to planting as well as in-crop for greater consistency of control in both conventional and conservation tillage situations (Johnson et al., 2010). Use of dicamba, in addition to glyphosate and the other herbicide options currently labeled for use on soybean and cotton, provides more options to implement diversified weed management programs to control a broad spectrum of grass and broadleaf weed species (Johnson et al, 2010). The availability of dicamba for use on dicamba and glyphosate tolerant crops provides: 1) growers with an opportunity for an efficient, effective weed management system; 2) an effective tool for the management of glyphosate resistant weeds that helps to conserve reduced tillage practices; 3) an option to delay or prevent further resistance to glyphosate and other critically important soybean herbicides, in particular herbicides in the ALS and PPO class of chemistry; 4) excellent crop safety; and 5) soybean growers with effective weed control systems necessary for production yields to meet the growing needs of the food, feed, and industrial markets necessary to maintain the United States' leading global position in key crop production.

ii. Environmental risk profile and safety for humans, animals and non-target organisms.

The toxicology or risk profile of dicamba has been extensively reviewed (U.S. EPA 2009). Dicamba does not pose any unusual toxicological concerns and is not carcinogenic (Durkin and Bosch 2004; European Commission 2008; U.S. EPA 2009). U.S. EPA completed the reregistration of dicamba in 2006. The Reregistration Eligibility Decision (RED) document for dicamba and its associated salts concluded that a high level of confidence exists for the dicamba hazard database and the reliability of these data necessary to support the required finding for continued registration. The dicamba RED document, and the related EPA Health Effects Division (HED) chapter (U.S. EPA 2005a), provide a detailed overview of the toxicological properties of dicamba.

U.S. EPA evaluated the potential risks to humans from the use of dicamba as a part of the dicamba RED, concluding that aggregate exposure to dicamba, defined as dietary (food and water) and non-occupational (residential and recreational) exposures, meet the FIFRA determination of no unreasonable adverse effects and the FFDCA determination for reasonable certainty of no harm to human health. EPA has conducted acute and chronic dietary (food and water) risk assessments for dicamba based on a theoretical worst case exposure estimate. For food, this estimate assumes that dicamba is used on 100 percent of all the crops on which the pesticide is currently approved for use. It further assumes that the resulting pesticide residues found on all harvested food and feed crops and derived animal food commodities (e.g., meat and milk) are at the level of the legally established tolerance (i.e., the maximum allowable pesticide residue level). Residues of dicamba are defined as dicamba and its metabolites 5-hydroxy dicamba and 3,6-dichlorosalicylic acid (DCSA). For water, EPA assumed that dicamba could potentially move offsite to adjacent surface water bodies as a result of drift or runoff, or move through soil to groundwater. Since the estimated concentrations in groundwater were significantly lower compared to surface water, surface water estimates were used in the worst case dietary assessments. Surface water estimates were generated with the conservative models using an exaggerated application rate that is 2.8 times higher than the current maximum single application rate established in the dicamba RED (U.S. EPA 2005a; b; c; 2009).

A comprehensive evaluation and risk assessment conducted by U.S. EPA concluded that dicamba has low toxicity to mammals, is not a carcinogen, does not adversely affect reproduction and development, and does not bioaccumulate in mammals (U.S. EPA 2009). An ecotoxicological risk assessment concluded that the use of dicamba does not pose an unreasonable risk of adverse effects to non-target species, such as birds and fish, when used according to label directions, nor does it pose an unreasonable risk of adverse effects to insects outside of the application area (U.S. EPA 2009). Furthermore, outside the cultivated fields, U.S. EPA concluded that dicamba is unlikely to affect forbs and beneficial arthropods that are dependent on plants for survival (U.S. EPA 2009).

iii. Sustained environmental and economic benefits.

The Weed Science Society of America (WSSA) has compiled peer reviewed best management practices (BMPs) to reduce the risk of weeds developing herbicide resistance (WSSA, 2018). Two of the recommendations are directly relevant to the benefits of OTT applications of dicamba on dicamba-tolerant crops. The authors advise growers to "(u)se a diversified approach toward weed management focused on preventing weed seed production and reducing the number of weed seeds in the soil seedbank" and "(u)se multiple herbicide MOAs that are effective against the most troublesome weeds or those most prone to herbicide resistance." OTT applications of dicamba provide flexibility in application timing for an additional herbicidal site of action, thus providing growers more diversified weed management options.

Field trials conducted in cooperation with Southern Illinois University during 2017 compared the performance of diversified weed management systems in soybean that incorporated either OTT dicamba applications or OTT glufosinate applications. Systems that incorporated OTT dicamba demonstrated statistically significant advantages in broadleaf weed control at both canopy development and harvest. At canopy, weed management systems incorporating OTT dicamba resulted in 96 – 97% broadleaf weed control while weed management systems incorporating OTT glufosinate resulted in 90 – 95% weed control (Figure 3 in Appendix 1). At harvest, weed management systems incorporating OTT dicamba resulted in 96 – 97% broadleaf weed control while weed management systems incorporating OTT glufosinate resulted in 88 – 96% weed control (Figure 4 in Appendix 1). More thorough weed control reduces the potential for creating a weed seed bank that can emerge in subsequent years, increasing the risk of resistant weeds (WSSA, 2018). Appendix 2 presents details of field trial design and management.

While long term considerations such as limiting weed seed banks can motivate some growers to adopt diversified weed management practices, short term economic returns are often a significant consideration. Nearly two decades ago, Reddy and Whitting (2000) reported that soybean growers relied on OTT glyphosate as their sole mechanism of weed control following the introduction of glyphosate-tolerant soybeans largely because of economic considerations. The authors found that a post-emergence application of glyphosate produced similar weed control as a preemergent herbicide combined with glyphosate post-emergence. While economically advantageous in the short term, this practice encouraged the development of resistant weeds. It is reasonable to expect, therefore, that aligning economic incentives with long term management of resistant weeds will lead to greater adoption of diversified weed management practices.

Data from the 2017 field trials conducted with Southern Illinois University demonstrate that weed management systems incorporating OTT dicamba applications provide economic returns that support growers' motivation to diversify their weed management tactics. In addition to the weed control advantages noted above, diversified weed management systems that included OTT dicamba produced a statistically significant yield advantage of 5.8 bu/acre over weed management systems that included OTT glufosinate (Figure 7 in Appendix 1). Most importantly, this yield advantage translated into a $34 - $39/acre economic advantage for systems incorporating OTT dicamba applications even after accounting for greater system costs of $14 - $17/acre (Figure 9 in Appendix 1). Appendix 2 presents details of field trial design and management.

The availability of weed management systems that include OTT applications of dicamba mitigates the challenges of weed control after crop emergence. Soybean and cotton are both broadleaf plants as are two of the most impactful glyphosate resistant weeds, Palmer amaranth and waterhemp. Controlling broadleaf weeds in a broadleaf crop requires either a crop that can tolerate broadleaf herbicides or constraining herbicide application methods. In cotton, for example, herbicides that control broadleaf weeds required specialized spraying equipment, specific row spacing to accommodate interrow herbicide applications, and in some cases, preharvest intervals as long as 100 days (McGinty et al., 2016).

According to U.S. EPA: "The need for additional tools to manage … resistant weeds has become important as resistance to both glyphosate and other herbicides has become a significant financial, production and pest management issue for many cotton and soybean growers (U.S. EPA, 2016)."

EPA further stated: "However, resistance to glyphosate, the current market leader in soybeans and cotton, is having severe economic consequences in soybean and cotton production. The Weed Science Society of America and other weed control experts warn that the problem of glyphosate resistance is increasing, and that significant economic consequences will continue to increase without effective alternatives for weed control."

Without additional herbicidal sites of action such as dicamba, the presence and spread of glyphosate resistant weed species will continue. In fact, left unchecked, USDA estimated the cost of glyphosate resistant weeds to soybean farmers at approximately$20/acre (Livingston et al., 2015).

In addition to avoiding such added production costs now, the use of additional herbicidal sites of action reduces selection pressure on glyphosate as well as other classes of herbicides, thus preserving the effectiveness of herbicides for production growers well into the future (Tranel et al., 2015).

Regarding the potential for off-site movement of OTT dicamba applications to cause agronomic and economic impacts, two previous reports addressed these topics in detail (Monsanto Company, 2018 a, b).

In terms of environmental benefits, dicamba's complementary and supplementary postemergence activity to glyphosate provides improved postemergence weed management options and thus supports more sustainable conservation tillage practices because postemergence herbicide options are generally preferred by growers (Fawcett and Towery 2002). Tillage causes widespread soil disturbance causing erosion and topsoil loss, impacting the sedimentation and turbidity of streams. EPA identified sedimentation and turbidity as two of the top 10 causes of impairment to surface water in the U.S.; similarly in 2007, EPA identified sedimentation/siltation as a leading cause of impairment to rivers and streams in particular (U.S. EPA, 2007; 2009). EPA has projected conservation tillage to be "the major soil protection method and candidate best management practice for improving surface water quality" (U.S. EPA, 2002). EPA identifies conservation tillage as the first of its CORE4 agricultural management practices for water quality protection (U.S. EPA, 2007).

Conclusion

Weeds with resistance to herbicides commonly used with herbicide tolerant crops has greater interest in diversified weed management. In addition to crop rotation and mechanical control, published studies of herbicide resistant weed management recommend the simultaneous use of at least two herbicides with different sites of action. The latter approach is enabled by the adoption of crops with tolerance to both glyphosate and dicamba. Registering herbicides containing dicamba for use on these crops is in the public interest for three key reasons. First, growers need access to diversified weed management practices and the availability of OTT applications of dicamba meets this need. Second, dicamba exhibits low toxicity to humans and it can be used safely for weed control as required by FFDCA and FIFRA. Finally, registering dicamba will provide environmental benefits by enabling the continued use of reduced tillage practices and economic benefits by producing superior economic returns to growers. Aligning growers' economic outcomes with long term approaches to weed management will promote more widespread adoption of diversified weed management. The registration of OTT application of dicamba for use on dicamba and glyphosate tolerant crops represents a significant opportunity to extend the well-established benefits of herbicide tolerant cropping systems.

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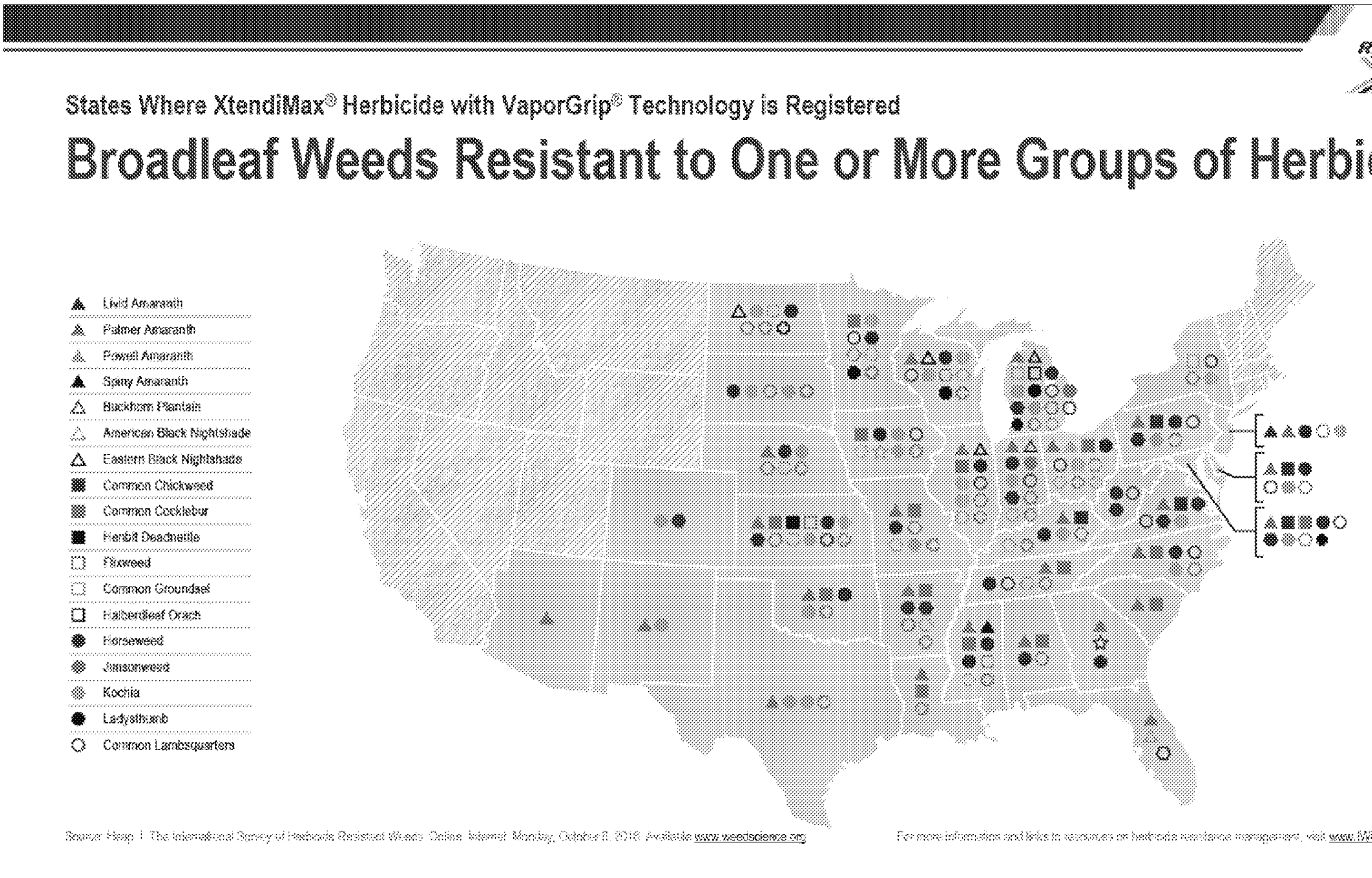

Figure 1. Broadleaf weeds resistant to one or more herbicides.

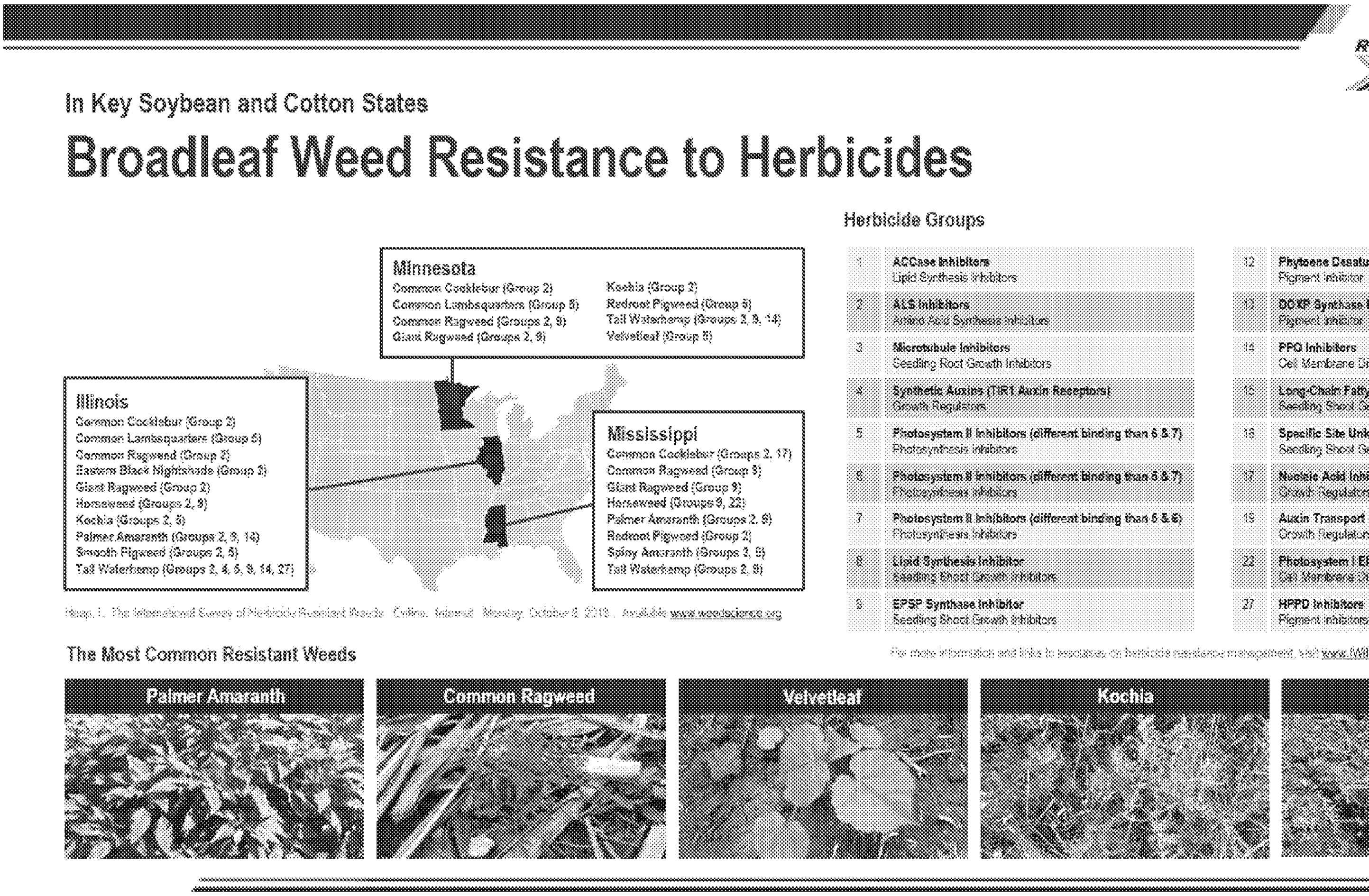

Figure 2. Broadleaf weeds resistant to herbicides in key soybean and cotton states.